

**Remarks**

Claims 1-120 are pending. Applicant notes with appreciation the allowance of claims 21-29, 34-44, and 86-92, and the conditional allowance of claims 4-9, 16-20, 30-33, 69, 75-76, 81, 85, 106-110, and 112-118.

Claims 1, 4, 7-8, 10, 16, 18, 21, 52, 54, 64, 69, 72-73, 75, 80-81, 85, 106-108, 110, 113-114 and 118-119 have been amended.

Claims 45-51, 55, 97-100 and 111 have been cancelled.

Claim 120 has been added.

Reconsideration of this application is respectfully requested in light of the foregoing amendments and the following remarks.

**Objections to the claims**

Claims 1, 7, 10, 21, 73, 113, and 118 have been objected to for various formality issues. Each claim has been amended as requested by the Examiner, with the exception of claim 1. In claim 1, the improperly spelled word "coplements" has been replaced with the word "complements," as opposed to the suggested word "compliments." Applicant respectfully submits that the suggested word is incorrect in the context of the claim and has amended the claim to reflect the appropriate word.

**Rejections under 35 U.S.C. § 112**

**35 U.S.C. § 112, First Paragraph**

Claims 13-15 stand rejected under 35 U.S.C. §112, first paragraph. Applicant respectfully directs the Examiner's attention to the last paragraph on page 13 of the application entitled "Detailed Description of Specific Embodiments." Lines 11-14 of that paragraph state that "[i]t has been discovered that a porous coating formed from nonspherical sintered beads provides very high friction between the outer surface of the shell and the bone, as well as

providing an excellent interaction with the cancellous bone of the joint, increasing the chances of bony ingrowth. One example of a suitable nonspherical sintered bead coating is that made of pure titanium, such as ASTM F-67. The coating can be formed by vacuum sintering.” Applicant submits that the above language sets forth the specifics of how and why each shell is coated with a biocompatible porous coating. Therefore, claims 13-15 should be allowed.

35 U.S.C. § 112, Second Paragraph

Claims 8, 30-33, 81 and 114-119 stand rejected under 35 U.S.C. §112, second paragraph. Applicant has amended the claims to overcome the rejections.

Rejections under 35 U.S.C. § 102

According to MPEP § 2131, to anticipate a claim, “[t]he identical invention must be shown in as complete detail as is contained in the ... claim”. Therefore, each reference used to sustain a rejection must disclose all of the elements of the rejected claim.

Claims 1, 2, 10-12, 97-100, 111 and 119

Claims 1, 2, 10-12, 97-100, 111 and 119 stand rejected under 35 U.S.C. §102(b) as being anticipated by Bryan et al. (U.S. Patent No. 5,674,296).

Claims 1, 2 and 10-12

The PTO provides in MPEP § 2131:

*To anticipate a claim, the reference must teach every element of the claim . . . .*

Therefore, with respect to claim 1, to sustain this rejection, the Bryan ‘296 patent must teach or suggest each element of the claim. However, the reference does not disclose “two rigid opposing shells, each having an outer surface adapted to engage the surfaces of the bones of a joint in such a way that movement of the shell relative to the bone surface is resisted by friction between the outer surface and the surface of the bone; an inner surface that is smoother than the

outer surface; and an edge between the outer surface and the inner surface[.]” Instead, the reference teaches “generally L-shaped supports, each support having a first concaval-convex leg, the first leg having an outer convex surface for engaging adjacent bone and a corresponding inner concave surface for retaining the resilient body, each support further having a second leg extending generally perpendicularly to the first leg and adapted for affixation to adjacent bone structure.” (col. 7, lines 16-22).

Therefore, the rejection of claim 1 is not supported by the Bryan ‘296 patent and should be withdrawn. Accordingly, claim 1 should be allowed. Claims 2 and 10-12 should also be allowed as they depend from and further limit claim 1.

Claims 97-100 and 111

Claims 97-100 and 111 have been cancelled.

Claim 119

With respect to claim 119, as stated previously, MPEP § 2131 requires that to sustain a rejection of claim 119, the Bryan ‘296 patent must teach or suggest each element of the claim. However, the reference does not teach or suggest “ $(\pm a, 0, 0)$ ,  $(0, \pm b, 0)$ , and  $(0, 0, \pm c)$  represent[ing] the x, y, and z intercepts of the surface, respectively, ... wherein a, b and c are the same for the outer and inner surfaces.”

Therefore, the rejection of claim 119 is not supported by the Bryan ‘296 patent and should be withdrawn.

Claims 45-63 and 72

Claims 45-63 and 72 stand rejected under 35 U.S.C. §102(b) as being anticipated by Böttner-Janz et al. (U.S. Patent No. 5,401,269).

Claims 45-51

Claims 45-51 have been cancelled.

Claims 52-54

With respect to claim 52, as stated previously, MPEP § 2131 requires that to sustain this rejection, the Büttner-Janz '269 patent must teach or suggest each element of the claim. However, the reference does not teach or suggest "the central body ha[ving] at least one convex contact surface."

Therefore, the rejection of claim 52 is not supported by the Büttner-Janz '269 patent and should be withdrawn. Accordingly, claim 52 should be allowed. Claims 53-54 should also be allowed as they depend from and further limit claim 52.

Claim 55

Claim 55 has been cancelled.

Claims 56-58

With respect to claim 56, as stated previously, MPEP § 2131 requires that to sustain this rejection, the Büttner-Janz '269 patent must teach or suggest each element of the claim. However, the reference does not teach or suggest "an upper shoulder extend[ing] around a portion of the perimeter of the upper contact surface and a lower shoulder extend[ing] around a portion of the perimeter of the lower contact surface."

Therefore, the rejection of claims 56 is not supported by the Büttner-Janz '269 patent and should be withdrawn. Accordingly, claim 56 should be allowed. Claims 57-58 should also be allowed as they depend from and further limit claim 56.

Claims 59-61

With respect to claim 59, as stated previously, MPEP § 2131 requires that to sustain this rejection, the Büttner-Janz '269 patent must teach or suggest each element of the claim. However, the reference does not teach or suggest "an upper shoulder extend[ing] around a

portion of the perimeter of the upper contact surface and a lower shoulder extend[ing] around a portion of the perimeter of the lower contact surface.”

Therefore, the rejection of claims 59 is not supported by the Büttner-Janz ‘269 patent and should be withdrawn. Accordingly, claim 59 should be allowed. Claims 60-61 should also be allowed as they depend from and further limit claim 59.

#### Claims 62-63

With respect to claim 62, as stated previously, MPEP § 2131 requires that to sustain this rejection, the Büttner-Janz ‘269 patent must teach or suggest each element of the claim. However, the reference does not teach or suggest “each shell ha[ving] a smooth inner surface that contacts the central body.”

Therefore, the rejection of claim 62 is not supported by the Büttner-Janz ‘269 patent and should be withdrawn. Accordingly, claim 62 should be allowed. Claim 63 should also be allowed as it depends from and further limits claim 62.

#### Claim 72

With respect to claim 72, as stated previously, MPEP § 2131 requires that to sustain this rejection, the Büttner-Janz ‘269 patent must teach or suggest each element of the claim. Claim 72, as amended, recites “at least one shell ha[ving] a rough outer surface that is not teeth-shaped.” (Emphasis added). In contrast, the Büttner-Janz ‘269 patent teaches that “top surfaces 4, which are in contact with the vertebral top surfaces facing them are provided with teeth 5 which penetrate into the vertebrae and thus bring about fixation of the prosthesis with respect to the vertebrae.” (col. 2, line 66 through col. 3, line 2) (Emphasis added).

Therefore, the rejection of claim 72 is not supported by the Büttner-Janz ‘269 patent and should be withdrawn.

#### Claim 74

Claim 74 stands rejected under 35 U.S.C. §102(b) as being anticipated by Ray et al. (U.S. Patent No. 6,123,465).

As stated previously, MPEP § 2131 requires that to sustain this rejection, the Ray '465 patent must teach or suggest each element of the claim. However, the reference does not teach or suggest "having at least one opening for the introduction of the lubricant into the structure." Instead, the reference actually teaches away from claim 74, stating that "each of the plurality of small openings 36 is small enough to prevent the hydrogel core 22 from escaping." (col. 7, lines 49-50).

Therefore, the rejection of claim 74 is not supported by the Ray '465 patent and should be withdrawn.

#### **Claims 77-79**

Claims 77-79 stand rejected under 35 U.S.C. §102(b) as being anticipated by Buettner-Janz et al. (U.S. Patent No. 4,759,766).

With respect to claim 77, as stated previously, MPEP § 2131 requires that to sustain this rejection, the Buettner-Janz '766 patent must teach or suggest each element of the claim. However, the reference does not teach or suggest "having a central retaining post extending therefrom and adapted to allow rotation of the shells relative to the central body." Instead, the reference teaches away from claim 77 and states that "[t]he convex center portion of the end plates can additionally be provided with pins which extend into the recesses of the spacing piece. The diameters of the recesses are designed so that they are larger than the diameters of the pins. Such a construction limits the maximum mobility of the intervertebral disc endoprosthesis and represents an additional precaution against an unintentional positional change of the spacing piece." (col. 3, lines 44-52).

Therefore, the rejection of claim 77 is not supported by the Buettner-Janz '766 patent and should be withdrawn. Accordingly, claim 77 should be allowed. Claims 78-79 should also be allowed as they depend from and further limit claim 77.

Claims 80, 83 and 84

Claims 80, 83 and 84 stand rejected under 35 U.S.C. §102(b) as being anticipated by Baumgartner et al. (U.S. Patent No. 5,370,697).

With respect to claim 80, as stated previously, MPEP § 2131 requires that to sustain this rejection, the Baumgartner '697 patent must teach or suggest each element of the claim. However, the reference does not teach or suggest "a radial stop extending generally axially from a portion thereof."

Therefore, the rejection of claim 80 is not supported by the Baumgartner '697 patent and should be withdrawn. Accordingly, claim 80 should be allowed. Claims 83 and 84 should also be allowed as they depend from and further limit claim 80.

Rejections under 35 U.S.C. §103

As provided in MPEP § 2143, "[t]o establish a prima facie case of obviousness, ... the prior art reference (or references when combined) must teach or suggest all the claim limitations." Furthermore, under MPEP § 2142, "[i]f the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness."

Claim 3

Claim 3 stands rejected over the combination of Bryan et al. (U.S. Patent No. 5,674,296) and DE 3343863A1 entitled "Joint endoprosthesis." Applicant respectfully traverses this rejection on the grounds that these references are defective in establishing a prima facie case of obviousness with respect to claim 3.

It is submitted that, in the present case, the Office Action cannot factually support a prima facie case of obviousness for the following reasons.

1. Even When Combined, the References Do Not Teach the Claimed Subject Matter

The Bryan '296 patent and DE 3343863A1 cannot be applied to reject claim 3 under 35 U.S.C. § 103 which provides:

*A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. (Emphasis added)*

Thus, as provided in MPEP § 2143, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. However, since neither of the cited references teaches or suggests (i) “two rigid opposing shells, each having an outer surface adapted to engage the surfaces of the bones of a joint in such a way that movement of the shell relative to the bone surface is resisted by friction between the outer surface and the surface of the bone; an inner surface that is smoother than the outer surface; and an edge between the outer surface and the inner surface”; or (ii) a body “comprising an outer surface, at least a portion of which has a shape that compliments and articulates with the shape of the inner surface of one or both rigid opposing shells to allow the inner surface of the rigid opposing shell and the outer surface of the central body to move easily with respect to each other within a constrained range of motion, but to resist such movement outside the constrained range of motion,” it is impossible to render the subject matter of claim 3 as a whole obvious, and the explicit terms of the statute cannot be met.

Therefore, for this reason alone, the rejection of claim 3 under 35 U.S.C. § 103 should be withdrawn.

2. Prior Art That Teaches Away From the Claimed Invention Cannot be Used to Establish Obviousness

The Bryan '296 patent states that “[t]o discourage and prohibit migration of fluids between the endoprosthesis 18 and adjacent parts of the anatomy, a seal member 110 is attached to the supports 32, 34 so as to surround the resilient body 20 comprised of the gasket 22 and nucleus 24, in accordance with another aspect of the invention. . . . Known sealing material can



be applied to the flexible sheet material so as to render the flexible sheet material substantially impervious to the passage of any fluid. A watertight seal is perfected when the seal 110 is glued or otherwise affixed to the legs 42, 44 and mediate portions of the legs 72, 74 as suggested in FIGS. 1-3.” (col. 4, lines 31-52). Such a fluid-prevention system clearly teaches away from claim 3, which teaches “a liquid lubricant, which occupies at least a portion of the cavity.”

Since it is well recognized that teaching away from the claimed invention is a per se demonstration of lack of prima facie obviousness, it is clear that the Examiner has not borne the initial burden of factually supporting any prima facie conclusion of obviousness.

Thus, for this reason alone, the rejection of claim 3 under 35 U.S.C. § 103 should be withdrawn.

3. The References Are Not Properly Combinable If Their Intended Function Is Destroyed

It is clear that the Bryan ‘296 and DE 3343863 patents are not properly combinable since if combined, their intended function is destroyed. In particular, if the Bryan ‘296 patent were made to include liquid lubricant in the seal member 110, such modification clearly destroys the purpose or function of the seal member 110—preventing the passage of any fluid. Therefore, one of ordinary skill in the art would not have found a reason to make the claimed modification.

For this reason alone, the rejection of claim 3 under 35 U.S.C. § 103 should be withdrawn.

4. The Combination of References is Improper

Assuming, arguendo, that none of the above arguments for non-obviousness apply (which is clearly not the case based on the above), there is still another compelling reason that the above-cited patents cannot be applied to reject claim 3 under 35 U.S.C. § 103.

§ 2142 of the MPEP provides:

*[T]he examiner must step backward in time and into the shoes worn by the hypothetical ‘person of ordinary skill in the art’ when the invention was unknown and just before it was made. . . . the examiner must then make a determination whether the claimed*

*invention 'as a whole' would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination . . . .*

Here, neither of the cited references teaches, or even suggests, the desirability of the combination since neither teaches the specific arrangement as claimed in claim 3.

Thus, it is clear that neither of the cited patents provides any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103 rejection.

In this context, the MPEP further provides in §2143.01:

*The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. (Emphasis added)*

In the above context, the courts have repeatedly held that obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination.

In the present case, it is clear that the combination arises solely from hindsight based on the invention without any showing, suggestion, incentive or motivation in either reference for the combination as applied to claim 3.

Therefore, for this reason alone, the Examiner's burden of factually supporting a prima facie case of obviousness has clearly not been met, and the rejection of claim 3 under 35 U.S.C. § 103 should be withdrawn.

#### **Claims 64 and 65**

Claims 64 and 65 stand rejected over the combination of Büttner-Janz et al. (U.S. Patent No. 5,401,269) and Walker (U.S. Patent No. 4,193,139). Applicant respectfully traverses this rejection on the grounds that these references are defective in establishing a prima facie case of obviousness with respect to claims 64 and 65.

Claim 64

Pursuant to MPEP § 2142 as set forth previously, it is submitted that, in the present case, the Office Action cannot factually support a prima facie case of obviousness for the following reasons.

1. Even When Combined, the References Do Not Teach the Claimed Subject Matter

As stated previously, 35 U.S.C. § 103 requires that when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. Claim 64, as amended, provides that the inner surfaces of the shells are machined. In contrast, Walker'139 teaches "[a]rcuate bearing surface 25 [being] polished smooth ...." (col. 3, lines 56-57) (Emphasis added). Further, the Office Action has conceded that Büttner-Janz '269 does not teach the inner surfaces of the shells 1 & 2 being machined or polished. Therefore, even when combined, the cited references does not teach or suggest the specific implant as claimed in claim 64.

Therefore, applicant respectfully submits that the combination of these references will not establish a prima facie case of obviousness. Accordingly, for this reason alone, claim 64 should be allowed.

2. The Combination of References is Improper

Assuming, arguendo, that the above argument for non-obviousness does not apply (which is clearly not the case based on the above), there is still another compelling reason that the above-cited patents cannot be applied to reject claim 64 under 35 U.S.C. § 103.

Contrary to the requirement of MPEP §2142 as set forth previously, neither of the cited references teaches, or even suggests, the desirability of the combination since neither teaches the specific arrangement as claimed in claim 64.

Thus, it is clear that neither of the cited patents provides any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103 rejection.

Further, contrary to the requirements of MPEP § 2143.01 and court holdings as set forth previously, it is clear that the combination arises solely from hindsight based on the invention without any showing, suggestion, incentive or motivation in either reference for the combination as applied to claim 64.

Therefore, for this reason alone, the Examiner's burden of factually supporting a prima facie case of obviousness has clearly not been met, and the rejection of claim 64 under 35 U.S.C. §103 should be withdrawn. Accordingly, claim 64 should be allowed.

Claim 65

Claim 65 should also be allowed as it depends from and further limits claim 64.

**Claims 66-68, 70-71 and 73**

Claims 66-68, 70, 71 and 73 stand rejected over the combination of Büttner-Janz et al. (U.S. Patent No. 5,401,269) and Ducheyne et al. (U.S. Patent No. 4,990,163). Applicant respectfully traverses this rejection on the grounds that these references are defective in establishing a prima facie case of obviousness with respect to claims 66-68, 70-71 and 73.

Claims 66-68 and 70-71

With respect to claim 66, pursuant to MPEP § 2142 as set forth previously, it is submitted that the Office Action cannot factually support a prima facie case of obviousness because the combination of references is improper.

Here, neither of the cited references teaches, or even suggests, the desirability of the combination.

Thus, it is clear that neither of the cited patents provides any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103 rejection.

Further, contrary to the requirements of MPEP §2143.01 and court holdings as set forth previously, it is clear that in the present case, the combination arises solely from hindsight based

on the invention without any showing, suggestion, incentive or motivation in either reference for the combination as applied to claim 66.

Therefore, the Examiner's burden of factually supporting a prima facie case of obviousness has clearly not been met, and the rejection of claim 66 under 35 U.S.C. § 103 should be withdrawn.

Accordingly, claim 66 should be allowed. Claims 67-68 and 70 -71 should also be allowed as they depend from and further limit claim 66.

Claim 73

With respect to claim 73, pursuant to MPEP §2142 as set forth previously, it is submitted that the Office Action cannot factually support a prima facie case of obviousness because the combination of references is improper.

Here, neither of the cited references teaches, or even suggests, the desirability of the combination since neither teaches the specific arrangements contained in claim 73.

Thus, it is clear that neither of the cited patents provides any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103 rejection.

Further, contrary to the requirements of MPEP §2143.01 and court holdings as set forth previously, it is clear that in the present case, the combination arises solely from hindsight based on the invention without any showing, suggestion, incentive or motivation in either reference for the combination as applied to claim 73.

Therefore, the Examiner's burden of factually supporting a prima facie case of obviousness has clearly not been met, and the rejection of claim 73 under 35 U.S.C. § 103 should be withdrawn.

**Claim 82**

Claim 82 stands rejected over Baumgartner et al. (U.S. Patent No. 5,370,697). Applicant respectfully traverses this rejection on the grounds that such reference is defective in establishing a prima facie case of obviousness with respect to claim 82.

Claim 82 should be allowed at least because it depends from and further limits claim 80, which should be allowed as stated previously.

Further, assuming, arguendo, that the above argument for non-obviousness of claim 82 does not apply (which is clearly not the case), there is still another compelling reason why the Baumgartner patent '697 cannot be applied to reject claim 82 under 35 U.S.C. § 103.

In *In re Aller*, the court held that no invention was involved in discovering optimum ranges of a process by routine experimentation. The court reasoned that a skilled chemist who chose to experiment with the reference process would undoubtedly try the conditions defined by the claims. However, with respect to claim 82, the Baumgartner patent '697 does not define any conditions with respect to the distance of the stop. Further, unlike our application, *In re Aller* deals with a chemical patent where experiments of varied substance concentration and temperature occur routinely.

Therefore, the Examiner's burden of factually supporting a prima facie case of obviousness has clearly not been met, and the rejection of claim 82 under 35 U.S.C. § 103 should be withdrawn.

**Claims 93-96, 101-103 and 111**

Claims 93-96, 101-103 and 111 stand rejected over the combination of Bryan et al. (U.S. Patent No. 5,674,296) and Buechel et al. (U.S. Patent No. 5,868,796). Applicant respectfully traverses this rejection on the grounds that these references are defective in establishing a prima facie case of obviousness with respect to claims 93-96, 101-103 and 111.

Claims 93-96, 101, 103 and 111

With respect to claims 93-96, 101, 103 and 111, pursuant to MPEP § 2142 as set forth previously, it is submitted that the Office Action cannot factually support a prima facie case of obviousness because the combination of references is improper.

Here, neither of the cited references teaches, or even suggests, the desirability of the combination since neither teaches the specific arrangements contained in claims 93-96, 101, 103 or 111.

Thus, it is clear that neither of the cited patents provides any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103 rejection.

Further, contrary to the requirements of MPEP § 2143.01 and court holdings as set forth previously, it is clear that in the present case, the combination arises solely from hindsight based on the invention without any showing, suggestion, incentive or motivation in the reference for the combination as applied to claims 93-96, 101, 103 and 111.

Therefore, the Examiner's burden of factually supporting a prima facie case of obviousness has clearly not been met, and the rejection of claims 93-96, 101, 103 and 111 under 35 U.S.C. § 103 should be withdrawn. Accordingly, claims 93-96, 101, 103 and 111 should be allowed.

Claim 102

Claim 102 should also be allowed as it depends from and further limits claim 101.

Claims 104-105

Claims 104-105 stand rejected over the combination of Bryan et al. (U.S. Patent No. 5,674,296) and Walker (U.S. Patent No. 5,593,445). Applicant respectfully traverses this rejection on the grounds that these references are defective in establishing a prima facie case of obviousness with respect to claims 104-105.

Claim 104

With respect to claim 104, pursuant to MPEP § 2142 as set forth previously, it is submitted that the Office Action cannot factually support a prima facie case of obviousness because the combination of references is improper.

Here, neither of the cited references teaches, or even suggests, the desirability of the combination since neither teaches the specific arrangement as claimed in claim 104.

Thus, it is clear that neither of the cited patents provides any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. § 103 rejection.

Further, contrary to the requirements of MPEP § 2143.01 and court holdings as set forth previously, it is clear that in the present case, the combination arises solely from hindsight based on the invention without any showing, suggestion, incentive or motivation in either reference for the combination as applied to claim 104.

Therefore, the Examiner's burden of factually supporting a prima facie case of obviousness has clearly not been met, and the rejection of claim 104 under 35 U.S.C. §103 should be withdrawn. Accordingly, claim 104 should be allowed.

Claim 105

Claim 105 should also be allowed as it depends on and further limits claim 104.



**Conclusion**

As a result of the foregoing, it is respectfully asserted that pending claims 1-44, 52-54, 56-96, 101-110, and 112-120 are in condition for allowance. Should the Examiner deem that any further amendment is desirable to place this application in condition for allowance, the Examiner is invited to contact the undersigned at the below listed telephone number. Also, Deposit Account No. 08-1394 may be used for any over or under payments.

Respectfully submitted,

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